Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC, Plaintiff, v. XAVIER BECERRA, in his capacity as Secretary of the United States Department of Health and Human Services, Defendant.	)	Case No. 1:22-cv-00397-JMC

DEFENDANT'S SURREPLY IN FURTHER SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Plaintiff's Reply in Support of its Cross-Motion for Summary Judgment ("Pl. Reply") raises new arguments in its continued effort to assert its mechanical occlusion chemically assisted ablation ("MOCA") services should be covered under the Medicare program despite the fact they were not scientifically proven effective. ECF No. 30. In support of its argument the Secretary allegedly violated agency regulations, Plaintiff misleadingly focuses on an *interim* administrative decision (the ALJ decision) when the Court's jurisdiction is limited to reviewing the *final* administrative decision of the Secretary (the Medicare Appeals Council decision). 42 U.S.C. § 1395ff(b)(1)(A). The Secretary's final administrative decision cannot violate the regulations at 42 C.F.R. §§ 405.1032 and 405.1018, as Plaintiff contends, because those regulations govern *interim* administrative proceedings.[1]

Also misleading is Plaintiff's contention the Secretary should be legally bound by erroneous administrative decisions issued by one ALJ. Plaintiff fails to address the fact that ALJ decisions do not constitute "final judgments" for purposes of collateral estoppel. *Prosser v.*

[1] The regulation at 42 C.F.R. § 405.1032 governs ALJ hearing procedures and the regulation at 42 C.F.R. § 405.1018 governs the submission of evidence in ALJ hearings.

Azar, No. 20-C-194, 2020 WL 3642315, at *5 (E.D. Wisc. July 6, 2020) *aff'd on other grounds*, *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021). The Secretary addresses each of Plaintiff's new arguments below.

First, Plaintiff contends the Secretary raised a "new" basis for denying the Medicare claims at issue after the ALJ hearing took place and that the Secretary's position allegedly permits the introduction of surprise bases that "would render both the statutory and regulatory scheme contradictory and nonsensical, violating fundamental standards of statutory and regulatory construction." Pl. Reply at 3 (citation omitted). According to Plaintiff, the Secretary's position would allow the government to raise new issues after the ALJ hearing without limitation even though the claimant has no prior notice of the issue and Plaintiff would have no opportunity to present evidence to rebut the new issue. *Id.* at 2-3. However, Plaintiff's contention rests on multiple false assertions.

The Medicare Appeals Council's denial of the Medicare claims at issue for lack of medical necessity was not a new issue; several lower-level administrative decisions denied Plaintiff's claims on this basis. *See* Def. Mem. L. in Supp. Mot. for Summ. J. (ECF No. 18-1) at 9-14. Regardless, where the Medicare Appeals Council reviews an ALJ decision by way of a CMS referral, as is the case here, the Council is authorized to accept such review only if "the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(2). Moreover, the Council is limited to considering only "the exceptions raised by CMS" in its review of the ALJ decision. *Id.* Consequently, it is not true the Council has an unfettered ability to raise new issues after the ALJ hearing.

Yet, the Medicare Appeals Council does have the power to conduct *de novo* review of ALJ decisions and, specifically, to correct errors of law. 42 C.F.R. §§ 405.1100(c),

405.1110(c)(2). To the extent the Medicare Appeals Council identifies, either on its own motion or based on a CMS referral, an error of law or fact *that has not been adequately addressed in the administrative proceedings below*, the Council has the power to remand the case to an ALJ or attorney adjudicator for further proceedings. 42 C.F.R. §§ 405.1110(d).

There was no need for the Medicare Appeals Council to remand the case to the ALJ here because Plaintiff already had ample opportunity to challenge the denial based on lack of medical necessity in several lower-level proceedings. *See* Def. Mem. L. in Supp. Mot. for Summ. J. at 9-14. Thus, it is not true that providers are unable to present or address new issues that are raised; providers can do so through the remand process when genuinely "new" issues arise late in the administrative proceeding process. Moreover, though this case did not require remand, Plaintiff nevertheless did address the issue CMS raised in its referral and it is included as part of the certified administrative record. CAR 4743-45.

Additionally, Plaintiff contends the lower-level administrative denials based on lack of medical necessity failed to provide meaningful notice since there are 65 ways a claim can be medically unnecessary. Pl. Reply at 3 n.2. Plaintiff's argument fails. It is the provider who bears the burden of proof to demonstrate claims for Medicare services were medically reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A) (excluding from Medicare coverage services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury") and 42 U.S.C. § 1395l(e) (excluding payment unless information necessary for payment provided).

CMS does not bear the burden of proof to demonstrate the claims for Medicare services were *not medically reasonable and necessary*. Here, the erroneous issues concerning the inapplicable LCD and the inapplicable billing codes were injected after Plaintiff already had the burden to demonstrate the medical necessity of the claimed services. *See* Def. Mem. L. in Supp. Mot. for Summ. J. at 12-14 (showing these erroneous issues were injected at the Redetermination

and Reconsideration level). Accordingly, Plaintiff cannot use the injection of legal errors into the course of the administrate process to excuse its initial failure to meet the burden of proof to show the claimed services were medically reasonable and necessary. 42 U.S.C. §§ 1395l(e), 1395y(a)(1)(A).

Plaintiff's contention the Secretary should be collaterally estopped from denying the Medicare claims at issue based on erroneous administrative decisions issued by one ALJ is also based on misleading assertions. For example, Plaintiff incorrectly asserts that courts have "confirm[ed] [the] presumption that administrative decisions are subject to issue preclusion." Pl. Reply at 4 (citing *Astoria Fed'l Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 107-08 (1991); *B&B Hardware*, 575 U.S. 138, 148-51 (2015)). However, this mischaracterization of case law cannot mask or excuse Plaintiff's own failure to show ALJ decisions here constitute "final judgments" for purposes of collateral estoppel. *Prosser*, 2020 WL 3642315, at *5.

Additionally, Plaintiff has created a false narrative that Congress intended for collateral estoppel to apply to administrative decisions concerning Medicare benefit determinations, or at least that Congress did not intend to preclude collateral estoppel here. But Congress created a complex administrative review process for Medicare claims determinations *in addition to a formal judicial review process*. 42 U.S.C. § 1395ff. Since Congress explicitly provided formal judicial review of Medicare claims determinations in federal court, the informal administrative review process set forth in the Medicare statute was never intended to bind the Secretary.[2]

Plaintiff claims the Appropriations Clause does not prohibit collateral estoppel, falsely

[2] Indeed, the fact Congress established an administrative appeal process and a judicial review process clearly demonstrates Congress did not intend the administrative appeal process to constitute a situation where the Secretary acts in a "judicial capacity," as Plaintiff contends. There is no need for the Secretary to serve in a "judicial capacity" under a Medicare claims appeal framework that contains formal judicial review in federal court.

asserting there is statutory authority for the appropriation of funds here. Pl. Reply at 8. However, the Medicare statute explicitly prohibits payment for services that are not medically reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A). Because the services at issue here were not medically reasonable and necessary, the Medicare statute prohibits reimbursement regardless of an erroneous ALJ decision to the contrary. And, the collateral estoppel doctrine cannot be used to overcome the Medicare statute's prohibition on payment for services that are not medically reasonable and necessary.

Contrary to Plaintiff's assertions, the Secretary notes for the record that it has not conceded that any elements of collateral estoppel were met. Pl. Reply. at 17; Def. Reply at 17-23 (describing Plaintiff's failure to establish collateral estoppel elements). Nor did the Secretary fail to dispute "that the prior decisions determined that MOCA is a Medicare covered benefit or that a finding that a device/service was 'medically reasonable and necessary' is a prerequisite to finding that a device/service is covered under the statute." Pl. Reply at 15-16. Nor did the Secretary "fail[] to dispute that the issue of Medicare coverage of the MOCA procedure was decided in the prior cases." *Compare* Pl. Reply at 15-16, *with* Def. Reply at 18-19.

Respectfully submitted,

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